Remarks

A. Information Disclosure Statement

The Examiner is thanked for correcting the error on the 1449 form where reference to US 32,991 should have been US RE 32,991.

B. Specification

The Examiner has noted out that the trademarks LYCRA and BEN-GAY have been used and pointed out that they should be capitalized and accompanied by their generic terminology. The specification has been corrected.

C. Support for Amendments

Support for identifying the gel as "a silicone" gel may be found at page 2, line 5, page 6, line 20, and page 7, lines 3-7.

Support for identifying the loop portion as "a stretchable loop" may be found at page 3, lines 9-11 where "rigid yet stretchable loop portions that have a modulus of elasticity of about 50%, with no stretch memory" are described.

Support for identifying the material as "a composite" may be found on page 1, at lines 15 to 18 where a "composite material consisting of two layers" is described.

D. Rejection § 102(b) Over U.S. 6,153,946 (Docter)

Claims 6-7 and 28-33 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. With respect to Claim 6, Docter discloses at col. 2, lines 17-24 a stretchable, supportive wrap 10. Which has a gel layer 14, a stretchable carrier 12, and closure strips 16. It has been held that the prior art inherently performs a claimed method when that prior art meets the structural limitations of the article of the claimed invention and is used in normal and usual operation (see MPEP 2112.02). It is considered normal and usual operation to stretch a stretchable wrap around a portion of the body and to then secure the wrap in a

closed position with closure strips or fasteners. The Examiner also points to Docter's disclosure at col. 3, lines 8-14 for mention of this operation therefore believes that Docter anticipates the claimed method. With respect to Claim 7, Docter discloses at 3, lines 42-62 a gel layer 14 which comprises a hydrogel. With respect to Claims 28-33, the Examiner points out that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitation.

E. Applicants' Response to § 102(b) Rejection Over U.S. 6,143,946

Claims 6-7 and 28-33 have been rejected as anticipated by U.S. 6,143,946 (Docter). It is respectfully submitted that Claims 6-7 and 28-33 which cover a claimed method for providing musculo-skeletal support cannot be anticipated by the therapeutic mat of Docter.

First, Docter's gels are hydrogels which absorb fluids. See the discussion at col. 2, lines 42-53. The claimed gels are silicone gels which are known to be <u>hydrophobic</u>. The claimed silicone gels do not break down or change characteristics in the presence of water or sweat (see the discussion at page 8, lines 2-4).

Second, Applicants' carrier is an elastic and supportive carrier which is the stretchable loop portion of a hook and loop fastener. Docter's carrier is a material such as spandex (see column 2, line 25 and 32) which is "slightly elastic" or "relatively elastic" (see column 1, line 61 and col. 2, line 25, emphasis added). Docter's carrier is not supportive.

No matter how the therapeutic mat of Docter is secured to a body part, a "slightly elastic" carrier having a hydrogel stuck on one surface can not anticipate Applicants' stretchable, supportive wrap where a silicone gel is bonded to an elastic and supportive carrier which is the stretchable loop portion of a hook and loop fastener.

F. §103(a) Rejection over U.S. 6,143,946

Claims 8, 9 and 34-36 were rejected under 35 U.S.C. 103(a) as obvious over U.S. 6,143,946 (Docter).

With respect to Claims 8 and 34, the Examiner states that Docter discloses the claimed invention except for the gel layer comprising a silicone gel which can be a polydiorganosiloxane resin. The Examiner notes that Applicants disclose that: "There is no reason to limit our device to silicone gel, if there are other gels that provide clinical benefit." Docter discloses at column 2, lines 42 – 43 that the hydrogel 14 is bacteriostatic (i.e., inhibits the growth and multiplication of bacteria). Thus, the Examiner believes, based on Applicant's own admission, that the hydrogel disclosed by Docter is equivalent to the claimed silicone gel and not patentably distinct from the prior art. With respect to Claim 9, the Examiner believes that Docter discloses the claimed invention except for the stretchable carrier 12 having an elastic modulus of about 50%. Docter discloses that the stretchable carrier 12 is elastic enough to cover a body part yet inelastic enough to maintain the wrap in a fixed position (citing col. 3, lines 32-41). Hence, the Examiner believes it would have been obvious to one of ordinary skill in the art to provide the stretchable carrier with an elastic modulus of about 50%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. With respect to Claim 35, the Examiner states that Docter discloses that the gel layer 14 may comprise therapeutic additives (citing col. 2, line 54col. 3, line 7). With respect to Claim 36, the Examiner states that Docter discloses that the therapeutic additives may include emollients (citing see col. 1 lines 25-34; col. 2, line 54; col. 3, line 7).

G. Applicants' Response To § 103(a) Rejection Over U.S. 6,143,946

It is respectfully submitted that Applicants have not admitted their gels are the same as the hydrogels of Docter. Hydrophilic and hydrophobic gels are <u>not</u> equivalent. Applicants' <u>hydrophobic</u> silicone gels will not break down or change <u>characteristics</u> in the <u>presence of water</u>. As amended, the claims are limited to silicone gels which clearly are not obvious over Docter for the reasons discussed above.

H. § 103(a) Rejection Over U.S. 6,143,946 In View of U.S. 4,991,574

Claims 8, 9, and 34-37 are rejected under 35 U.S.C. §103(a) as obvious over U.S. 4,991,574 (Docter) in view of US 4,991,574 (Pocknell).

With respect to Claim 8, the Examiner states that Docter discloses the claimed invention except for a gel layer that is a silicone gel and Pocknell discloses a stretchable, supportive bandage comprising a

gel layer 2 bonded to a stretchable carrier 3 (citing col. 1, lines 57-61 and Figure 1). The Examiner states that Pocknell further teaches the use of a silicone gel layer to aid in the treatment of hypertrophic scarring (citing col. 1, lines 42-46). Hence, the Examiner believes that it would have been obvious to one of ordinary skill in the art to modify the wrap of Docter in order to provide for a silicone gel as taught by Pocknell since doing so would allow the wrap to aid in the treatment of hypertrophic scarring. With respect to Claim 9, the Examiner believes that Docter discloses the claimed invention except for the stretchable carrier 12 having an elastic modulus of about 50%. The Examiner points out that Docter discloses that the stretchable carrier 12 is elastic enough to cover a body part yet inelastic enough to maintain the wrap in a fixed position (citing col. 3, lines 32-41). Hence, the Examiner believes that it would have been obvious to one of ordinary skill in the art to provide the stretchable carrier with an elastic modulus of about 50% since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. With respect to Claim 34, the Examiner notes that Pocknell teaches that the silicone gel may be a polydiorganosiloxane resin (citing col. 2, lines 4-32). With respect to Claim 35-36, the Examiner points out that Pocknell discloses that the wrap 10 may include additives typically employed in the treatment of burns and wounds (citing col. 4, lines 26-35). With respect to Claim 37, the Examiner notes that closure strips 16 are approximately the same width as the wrap 10 (citing Figure 4, and col. 3, lines 8-22).

I. Applicants' Response To § 103(a) Rejection Over U.S. 6,143,946 In View of U.S. 4,991,574

It is respectfully submitted that Pocknell's teachings regarding the silicone gel being a polydiorganosiloxane, the inclusion of additives in the silicone gel, and the use of closure strips (which are not even the hook portion of a hook and loop fastener) do not cure the deficiencies of Docter who teaches a hydrophilic, not hydrophobic gel, and a carrier which is not elastic and supportive.

J. Allowable Subject Matter

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 10 has been rewritten as suggested.

Claims 11-12, 14-15, and 38-42 are allowed. The Examiner is thanked for the allowance of Claims 11-12, 14-15, and 38-42...

The Examiner notes that the art of record teaches bandages or wraps with layers comprising silicone as well as elastic and supportive materials in order to provide simultaneous application of silicone and pressure therapies; however, this art fails to teach a wrap comprised of an elastic hook-and-loop-type support with a coating of silicone gel. The Examiner concludes that the art of record fails to teach a method comprising the use of a wrap comprised of a silicone gel and a hook and loop support. As amended, the remaining claims should be patentable for the same reasons since Claim 6 and the claims dependent thereon all call for a silicone gel layer bonded to an elastic and supportive carrier which is the stretchable loop portion of a hook and loop fastener.

K. <u>Drawings</u>

In Serial No. 09/931,974 (the parent application), the drawings were objected because the Examiner believed reference characters "5" and "40" were both used to designate the same gel layer. Reference "40", however, is the uncured gel compound which has been applied to the stretchable carrier 10 by passing the carrier onto a bath of uncured gel material as shown in Figure 5 or by depositing the uncured gel material onto the stretchable carrier as shown in Figure 6. In contrast, reference "5" in Figure 2 is the cured gel layer. Note the heating element in both Figures 5 and 6 where the gel is cured. See also the text at page 12, lines 7-8 as well as lines 16 to 18 regarding combining the gel and carrier and then curing the combined carrier and gel in a heating oven.

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The reference to "heating element" in Figures 6 and 7 will be changed to reference character "50" and the specification has been amended to include this reference number. If requested, corrected drawings will be provided where Figure 5 precedes Figure 6.

L. Closing

Entry of this amendment and an early allowance are respectfully requested. No new matter is presented.

Respectfully submitted,

Date:

april 29, 2005

Margaret B. Kelley
Margaret B. Kelley

Reg. No. 29,181

Clifford Chance US LLP 31 West 52nd Street New York, NY 10019

Telephone: (212) 878-3145